

### **REMARKS/ARGUMENTS**

This Amendment is submitted in response to the Office Action mailed April 10, 2007. At that time claims 1-11 were pending in the application. Claims 2 and 4 are cancelled by this paper, while claims 1, 3, and 5-8 are amended. Claims 1, 3, and 5-11 remain in the application, with claims 7-11 having been withdrawn as being directed to a non-elected invention.

Accordingly, claims 1, 3, 5 and 6 are presented for reconsideration by the Examiner in light of the amendments made above and the comments that follow.

### **FORMAL MATTERS**

A reference to the prior applications has been inserted into the specification as requested by the Examiner.

### **REJECTION UNDER 35 U.S.C. §112 SECOND PARAGRAPH**

The Examiner first rejected claims 1-6 as being indefinite under 35 U.S.C. §112, second paragraph. In particular, the Examiner objected to the utilization of the term "pharmaceutical combination," requesting instead the term "pharmaceutical composition." Office Action, p. 4. Applicants submit that the term "pharmaceutical combination" is set forth in the specification as comprising "a GLP-1 activity inhibitor and a GLP-2 activity enhancer." Specification, para. [0017]. The individual components of the combination are then carefully defined on pages 7-11. One skilled in the art, armed with the specification, would clearly understand that the term as it currently stands in the referenced claims.

The Examiner next stated that the terms "a GLP-2 activity" and "a GLP-1 activity" are unclear as failing to reference what activities are intended. Office Action, p. 4. Applicants note, however, that these phrases are incomplete as cited, and that the claims instead reference "a GLP-2 activity enhancer" and "a GLP-1 activity inhibitor." These terms are defined in pages 7-10 and 10-11, of the specification, respectively. Applicants assert that these terms are clear as defined in the specification.

Claim 6 is additionally rejected as indefinite based upon an assertion that kit claims require multiple elements, based upon a citation of *In re Venezia*. Applicants have reviewed the Venezia opinion (189 USPQ 149), and found no requirement of multiple elements. Indeed, a survey of several recently-granted patents containing kit claims showed many with single-element kit claims:

U.S. Patent No. 7,279,295, Claim 2. A diagnostic kit comprising as reagent the isolated protein according to claim 1.

U.S. Patent No. 7,279,562, Claim 7. An immunoassay kit for measuring the blood level of a rapamycin comprising a conjugate of any one of claims 1, 2 or 3, wherein the carrier is a detector carrier material.

U.S. Patent No. 7,273,744, Claim 3. A kit comprising a composition according to claim 2, optionally including instruction for the use of said composition.

Applicants therefore assert that the kit claim is in proper form as presently stated and requests its allowance.

#### **REJECTION UNDER 35 U.S.C. §112 FIRST PARAGRAPH**

The Examiner next rejects claims 1-6 under 35 U.S.C. §112, first paragraph, asserting that the specification does not reasonably provide enablement for the claims as recited. In order to further prosecution of the application, Applicants have amended claims 1 and 6-8 to remove language describing prevention of disease, and have further amended claim 1 to state that the pharmaceutical combinations include a GLP-2 receptor agonist and a GLP-1 receptor antagonist.

The Examiner asserts that the specification discloses food intake alone, and is thus insufficient to support the claims, stating that undue experimentation would be required to enable treatment of any other diseases or conditions. The MPEP is clear in its explanations that “[c]ompliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed.” MPEP §2164.02.

Indeed, prophetic examples may suffice in some circumstances. Further, "[t]he presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure." *Id.*

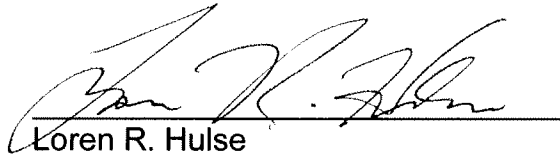
In the present application, the Applicants provided the study of intracerebroventricular peptide injections on food intake in mice. The Examiner noted the result obtained in the Tang-Christensen et al. article using a rat model, and asserted that it prevents one of skill from extrapolating the effect of enhancing GLP-2 induced anorexia in human or other species. Reference is further made to paragraph [0061] of the specification as indicating inhibitory effect of GLP-1 agonists on food intake in mice, rats and humans. Applicants note that paragraph [0061] sets forth considerations of mechanism of action, not difficulties correlating study results from one species to another. Indeed, as Applicants found through the intracerebroventricular injections and their *in vitro* studies, the effects of GLP-2 on feeding do not require the GLP-1 receptor, but may be modulated by affecting activity of GLP-1 receptor signaling. Applicants further provide teachings as to how methods and combinations according to the present invention may be adapted for use in different species. See, e.g., paragraph [0049]. As Applicants have provided examples and the example correlates with a use of the invention, Applicants submit that the claims are supported by the specification and should be allowed.

## **CONCLUSION**

Applicants respectfully assert(s) that claims 1, 3, 5 and 6 are thus allowable as amended herein, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Appl. No. 10/829,201  
Amdt. dated October 10, 2007  
Reply to Office Action of April 10, 2007.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Loren R. Hulse", is written over a horizontal line.

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